



Contact

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Key Competencies

- Medical Device Technology
- Product Development
- Production set-up
- Management
- Business planning
- System design and test
- Auditing
- MDR and MDD
- FDA, PMA and 510(k)
- ISO 13485
- IEC 60601-1
- ISO 14971 Risk Management
- Sterile manufacturing of single-use articles
- Machine learning and algorithm development
- Skin cancer diagnostics
- Bio-signals
- Image processing and DICOM
- X-ray and mammography
- Scrum development
- Automated testing
- Microstructure design and production

Fredrik Goldkuhl

Medical Device Management and System Design

Profile

More than 25 years of experience from international product development, production and quality assurance. Mainly within the medical device industry but also from environmental engineering.

I have long experience from working in large international organizations, as well as starting up R&D departments and production from scratch in small venture capital founded companies.

I have managed international development of numerous applications such as bio-signal detection for cancer diagnosis, x-ray, digital mammography, automated production, sterilized single-use disposables in plastics, grain analysis, gene therapy, heart catheterization, anesthetics, Li-ion batteries, and fuel cells.

My work has gained me extensive experience from quality and regulatory compliance with FDA, MDR and MDD.

As a person I am energetic, positive, practical, and focused. I enjoy working with people in a technical environment, to solve technical problems and develop commercially successful applications.

Professional Experience

2017 – present

Founder, Ecolgo AB

Management consultant assignments within medical device and environmental engineering industry

- 2021 – 2023, Project manager for MDR implementation in medical device industry.
- 2021, Project manager for development of a disposable Suture Tool.
- 2020 – 2021, *Global Director QA and Regulatory at Bactiguard AB.* Interim Global director for QA and regulatory organization in Sweden and Malaysia. Project manager for MDR implementation.
- 2018 – 2019, Implementation of QA system for companies in medical device industry.
- 2017–2018, *CXO and project manager at MyFC AB.* Member of company management. Project manager and system design engineer for a fuel-cell-powered range extender for battery-powered vehicles.

Language

Swedish, English, German and some Spanish

Interests

Family, wooden house design and renovation, travelling, hiking, kayaking, skiing, environmental issues and cooking. Football coach and Scout leader for kids.

2006 – 2017

Director Product development and production, SciBase AB

Overall responsible for research, product development and production at SciBase. Responsible for development of a unique device, method and algorithm for diagnosis of skin cancer and other skin-related diseases.

Responsible for the product design and production sections in a successful PMA application to FDA. Responsible for product design and production compliance with MDD and MDR.

Responsible for production setup of automated production lines for sterilized micro structured single-use electrodes in plastic.

2001 – 2005

Project manager and senior consultant, HotSwap AB

Project manager for customers in medical device, image processing, telecom and analysis industry. Most projects involved software, hardware and mechanical design and ran from conceptual studies into series production. Conducting business plans for several startup medical device manufacturers.

1996 – 2001

Project manager, Siemens Healthcare AB

Technical project manager for development of the first-generation digital mammography system. The project was conducted in cooperation with Fuji Medical in Japan and mammography clinics in US and Germany.

Project manager for developing a new generation of mobile X-ray generators.

1994 – 1996

Electronic design engineer, Siemens Healthcare AB

Design of real time systems for control of X-ray generators.

Education

2000 Economical program for engineers, Handelshögskolan in Stockholm

1989–1994 Master of Electrical Engineering, *Signal processing and measurement systems*, Lund Institute of Technology (LTH)

1990–1991 Officer in the reserves, Arméns Fältarbetsskola in Södertälje

Relevant corporate education

- Mickla executive coaching program, SciBase AB
- Production of injection molded plastics, HotSwap Jönköping AB
- ClearCase and Requisite Pro, Rational
- Auditing ISO 13485, Bactiguard AB
- SW image processing and DICOM, Fuji Medical Tokyo
- Management training program, Siemens-Eléma AB
- Application of Risk Analysis to Medical Devices, Stat-A-Matrix
- Good Manufacturing Practice (GMP), Siemens-Eléma AB